INITIAL REVIEW ENGINEERING REPORT [redacted]
PMN: 18-0227

Standard Review 9/26/2018
ENGINEER: Macek \ MLS
PV (kg/yr): [redacted]
Revision Notes / Assessment Overview: 9/24/2018 Standard Review: (1) Based on experience and understanding of the generic scenarios, the reasonably foreseen uses (modified polymers, preparation of biomass-based colloidal carbon; coating gravel pack sand with polymeric breaker; nanotextured silicone hydrogel lenses; anti-freeze composition; sequestering agents in detergents, and plasticizer retardant for concrete) would not result in significantly larger releases than the uses identified in the PMN (chemical intermediate and corrosion inhibitor [redacted]). The reasonably forseen uses may result in higher releases compared to USE1 (Chemical Intermediate), but are not expected to result in significantly higher releases compared to USE2 ([redacted]) because USE2 is assumed to result in 100% release. (2) For USE1, number of sites was fixed to reflect the basis (previously assesssed at [redacted] sites, but changed to [redacted] sites, as the estimate of [redacted] sites is split between USE1 and PROC2). (3) For USE 2, [redacted] release was fixed (previously incorrectly estimated release of [redacted] kg). //// 8/2/2018 Note: Based on discussion at scoping meeting, general population exposures were not assessed due to PMN substance hazard profile.

SUBMITTER: [redacted]
USE: Chemical intermediate for [redacted]

OTHER USES: [redacted] preparation of biomass-based colloidal carbon; [redacted] coating gravel pack sand with polymeric breaker; [redacted] nanotextured silicone hydrogel lenses; [redacted] anti-freeze compositions.

MSDS: Yes Label: No

Gen Eqpt: Provide adequate ventilation. Wear protective eye glasses for protection against liquid splashes. Wear suitable gloves if prolonged skin contact is likely. Wear impervious gloves (EN374).

Respirator: Normally no personal respiratory protection is necessary.

Health Effects: Causes skin irritation. Causes eye irritation.
TLV/PEL:

CRSS (07/09/2018):

Chemical Name: D-Glucaric acid

S-H20: [redacted]

VP: [redacted]

MW: 210.14 [redacted]

Physical State and Misc CRSS Info:

Neat: Solid Mfg: [redacted] Solution: [redacted] End Use: Destroyed; Solution: PMN substance in water. The submitter states that the diacid structure as drawn represents the solid form of the PMN substance. In aqueous solution, the substance exists as the diacid in equilibrium with lactone forms (such as OC(=O)C(O)C1C(O)C(O)C(=O)O1). They state that this equilibrium is transient in nature, incidental to storage of the aqueous solutions, and has no commercial purpose. In addition, the end use of the aqueous solution will generally push the equilibrium back to the diacid form.

Submitted Data: [redacted]

Estimated Data [redacted]

Estimated Data [STN/ACD Labs]: [redacted]

Estimated Data for lactone form of PMN substance [EPI with no MP entered, MW = 192.13, MF = C6 H8 O7, OC(=O)C(O)C1C(O)C(O)C(=O)O1]: BP = 421.20°C; VP = 2.98E-10 torr; WS = 1,000 g/L; log P = -2.03.

Consumer Use: No

SAT (concerns) :

Related Cases and Misc SAT Info:

Analogs: [redacted]

Migration to groundwater: Negligible

PBT rating: P0B0T0

Health: Other

Eco: 1 No releases to water

OCCUPATIONAL EXPOSURE RATING: [redacted]

NOTES & KEY ASSUMPTIONS:
Occupational exposure and environmental releases were estimated using the 9/30/2013 version of ChemSTEER tool. Input to ChemSTEER tool includes information from: the PMN submission, physical / chemical properties, relevant past cases. No SAT report was prepared at the time of this assessment. [redacted]. RAD performs a full assessment. [redacted] THe following different submitter past cases were referenced for consistency: [redacted] // MFG: RAD assessed releases from equipment cleaning (consistent with [redacted]), loading solid (consistent with [redacted]), sampling (consistent with [redacted]). RAD assessed dermal exposure (consistent with [redacted]) and inhalation exposure (consistent with [redacted]) during loading. // USE1: RAD assessed releases from unloading solid (consistent with [redacted]), and from container and equipment cleaning (consistent with [redacted]). RAD assessed dermal (consistent with [redacted]) and inhalation exposures (consistent with [redacted]) during unloading. // PROC2: Only past case [redacted] assessed a processing operation. RAD assessed releases from container and equipment cleaning (consistent with [redacted]). RAD assessed dermal exposure during unloading (consistent with [redacted]). // USE2: RAD assessed release from container cleaning and the wastewater treatment process (consistent with [redacted]). RAD assessed dermal exposure during unloading (consistent with [redacted]).

POLLUTION PREVENTION CONSIDERATIONS:
None.
EXPOSURE-BASED REVIEW: [redacted] ([redacted] criteria met)
1) # of workers exposed: [redacted] >1000? [redacted]
2) >100 workers with >10 mg/day inhalation exposure: [redacted]
3) (a) >100 workers w/1-10 mg/day inh. exp. & >100 days/yr: [redacted]
   (b) Routine Dermal Cont: >250 workers & >100 days/yr: [redacted]

INITIAL REVIEW ENGINEERING REPORT [redacted]

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Manufacturing: Batch

Number of Sites/ Location: [redacted]

[redacted]

Days/yr: [redacted]

Basis: Submission specifies [redacted] in [redacted] powder. RAD specifies [redacted] in product. CS calculates [redacted]

Process Description: Raw materials [redacted] (submission)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water
Output 2: [redacted]

to: On-site WWT (Submission)
from: Wastewater from Evaporation Process and Equipment Maintenance

basis: User-Defined Loss Rate Model. Submission estimates [redacted] is released to on-site WWT from equipment maintenance.

Water
Output 2: [redacted]

to: On-Site WWT (submission)
from: Sampling Liquid Product
basis: User-Defined Loss Rate Model. Submission estimates a total of 0.001 kg PMN/bt is released to on-site WWT from sampling activities.

Water or Air or Incineration or Landfill
Conservative: [redacted]

to: Water, Air, Incineration, or Landfill (Model)
from: Loading Solid Product into Transport Containers
basis: EPA/OPPT Solids Transfer Dust Loss Model. No dust controls are assumed as a worst case. Submission does not estimate releases from loading of solid PMN product into transport containers. RAD assesses release with standard model to uncertain media.

RELEASE TOTAL
[redacted]

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: [redacted]
Basis: Submission estimates a total of [redacted] workers are potenitally exposed from [redacted] activities. RAD assumes that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Particulate (non-volatile) (Class I)
Upper Bound:
> Potential Dose Rate: [redacted]
> Lifetime Average Daily Dose: [redacted]
> Average Daily Dose: [redacted]
> Acute Potential Dose: [redacted]
Number of workers (all sites) with inhalation exposure: [redacted]

Basis: Loading [redacted] Product into Transport Containers; OSHA PNOR PEL-Limiting Model. Cm = 14.7 mg/m3 over h = 8 hrs/day.

NOTE: The respirator class is: I. Particulate (including [redacted] or liquid droplets).

INHALATION MONITORING DATA REVIEW
1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): [redacted]
2)a) Exposure level > 1 mg/day? [redacted]
OR
b) Hazard Rating for health of 2 or greater? [redacted]
=> Inhalation Monitoring Data Desired? **No**

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at [redacted] concentration
High End:
> Potential Dose Rate: [redacted]
> Lifetime Average Daily Dose: [redacted]
> Average Daily Dose: [redacted]
> Acute Potential Dose: [redacted]
Number of workers (all sites) with dermal exposure: [redacted]
Basis: Loading Liquid Product into Totes; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

Exposure to Solid at [redacted] concentration
High End:
> Potential Dose Rate: [redacted]
> Lifetime Average Daily Dose: [redacted]
> Average Daily Dose: [redacted]
> Acute Potential Dose: [redacted]
Number of workers (all sites) with dermal exposure: [redacted]
Basis: Loading Solid Product into Transport Containers; EPA/OPPT Direct 2-Hand Dermal Contact with Solids Model.

INITIAL REVIEW ENGINEERING REPORT [redacted]

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Use 1: [redacted]

Number of Sites/ Location: [redacted]

unknown site(s)

Days/yr: [redacted]

Basis: Submission indicates a total of [redacted] sites for downstream processing (PROC2) and this USE1 operation. Because [redacted], RAD assumes [redacted]. PMN is [redacted] in raw material. RAD assumes [redacted] CS calculates [redacted] PMN/st-bt.

Process Description: [redacted] (per submission, past cases, and CRSS)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water or Air or Incineration or Landfill
Conservative: [redacted]

to: Water, Air, Incineration, or Landfill (model)

from: Unloading Solid Raw Material from Transport Containers

basis: EPA/OPPT Solids Transfer Dust Loss Model. No dust controls are assumed as a worst case. Submission does not estimate releases downstream of MFG. RAD assesses release with standard model to uncertain media.

Water or Incineration or Landfill
Output 2: [redacted]

to: Uncertain

from: Cleaning Solid/ Powder Residuals from Containers Used to Transport the Raw Material

basis: EPA/OPPT Solid Residuals in Transport Containers Model, CEB standard 1% residual. Submission does not estimate releases downstream of MFG. RAD assesses release with standard model to uncertain media.

Water or Incineration or Landfill
Output 1: [redacted]

Output 2: [redacted]

to: Uncertain

from: Equipment Cleaning Losses of Solids from Process Vessels

basis: User-Defined Loss Rate Model. Submission does not estimate this release. Per March 2015 guidance on assessing releases of a chemical intermediate from reactor cleaning, RAD assumes 95-99% reaction, with 1% residual. Therefore, [redacted].

RELEASE TOTAL
[redacted]

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: [redacted]

Basis: Submission does not estimate the number of workers potenitally exposed during this operation. RAD assesses a minimum default of [redacted] workers/site and that all workers perform all activities. RAD assumes that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Particulate (non-volatile) (Class I)
Typical:
> Potential Dose Rate: [redacted]
> Lifetime Average Daily Dose: [redacted]
> Average Daily Dose: [redacted]
> Acute Potential Dose: [redacted]
Worst Case:
> Potential Dose Rate: [redacted]
> Lifetime Average Daily Dose: [redacted]
> Average Daily Dose: [redacted]
> Acute Potential Dose: [redacted]
Number of workers (all sites) with inhalation exposure: 75

Basis: Unloading Solid Raw Material from Transport Containers; EPA Small Volume Handling Model, less than [redacted] of solid containing the PMN handled per site-day. This model does not calculate mass concentration (mg/m3) and associated exposure duration (hr/day).

NOTE: The respirator class is: I. Particulate (including solid or liquid droplets).

INHALATION MONITORING DATA REVIEW
1) Uncertainty (estimate based on model, regulatory limit, or data not specific to industry): [redacted]
2)a) Exposure level > 1 mg/day? [redacted]
OR
b) Hazard Rating for health of 2 or greater? [redacted]
=> Inhalation Monitoring Data Desired? **No**

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Solid at [redacted] concentration
High End:
> Potential Dose Rate: [redacted]
> Lifetime Average Daily Dose: [redacted]
> Average Daily Dose: [redacted]
> Acute Potential Dose: [redacted]
Number of workers (all sites) with dermal exposure: [redacted]
Basis: Unloading Solid Raw Material from Transport Containers; EPA/OPPT Direct 2-Hand Dermal Contact with Solids Model.

INITIAL REVIEW ENGINEERING REPORT [redacted]

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Processing 2: [redacted]

Number of Sites/ Location: [redacted]

unknown site(s)

Days/yr: [redacted]

Basis: Submission indicates a total of [redacted] sites for downstream processing (PROC2) and this USE1 operation. [redacted] in product. RAD assumes [redacted] CS calculates PMN use rate of [redacted]

Process Description: PMN unloaded ([redacted]) -> add to mixing vessel with other ingredients --> blend --> package into containers for customer use [redacted] (past cases and CRSS)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water or Incineration or Landfill
High End: [redacted]

to: Uncertain

from: Cleaning Liquid Residuals from Totes Used to Transport the Raw Material

basis: EPA/OPPT Bulk Transport Residual Model, CEB standard 0.2% residual. Submission does not estimate releases downstream of MFG. RAD assesses release with standard model to uncertain media.

Water or Incineration or Landfill
Conservative: [redacted]

to: Uncertain

from: Equipment Cleaning Losses of Liquids from a Single, Large Vessel

basis: EPA/OPPT Single Vessel Residual Model, CEB standard 1% residual. Submission does not estimate releases downstream of MFG. RAD assesses release with standard model to uncertain media.

RELEASE TOTAL
[redacted]

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: [redacted]
Basis: Submission does not estimate the number of workers potenitally exposed during this operation. RAD assesses a minimum default of 3 workers/site and that all workers perform all activities. RAD assumes that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

Air releases are negligible (VP < 0.001 torr) and generation of mists / aerosols is not expected during this operation.

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at [redacted] concentration

High End:

> Potential Dose Rate: [redacted]

> Lifetime Average Daily Dose: [redacted]

> Average Daily Dose: [redacted]

> Acute Potential Dose: [redacted]

Number of workers (all sites) with dermal exposure: [redacted]

Basis: Unloading Liquid Raw Material from Totes; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

INITIAL REVIEW ENGINEERING REPORT [redacted]

PMN: 18-0227

Use 2: [redacted]

Number of Sites/ Location: [redacted]

unknown site(s)

Days/yr: [redacted]

Basis: Past cases [redacted] estimate use rates of approximately [redacted], respectively. PMN is [redacted]l. Using past case use rates and days/yr, CS calcualtes [redacted], respectively. RAD assesses at least as many sites as [redacted], thus assesses [redacted] for this operation. RAD assumes mid-line of [redacted]. CS calculates [redacted].

Process Description: [redacted] (past cases and CRSS)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water
Output 2: [redacted]

to: POTW or surface water (per past cases)

from: Wastewater Treatment

basis: User-Defined Loss Rate Model. Per past cases [redacted], RAD assumes the remaining PV is release from the wastewater treatment process in treated water to POTW or surface water (depending on use site) and in sludge (depending on treatment efficiency). Note that PMN highly soluable in water, thus the majority of release is likely with the treated water. Per CRSS the PMN is not destroyed in the WWT process. LF = [redacted] (container cleaning) = [redacted].

Water or Incineration or Landfill
High End: [redacted]

to: Uncertain

from: Cleaning Liquid Residuals from Drums Used to Transport the Raw Material

basis: EPA/OPPT Drum Residual Model, CEB standard 3% residual. Submission does not estimate releases downstream of MFG. RAD assesses release with standard model to uncertain media.

RELEASE TOTAL
[redacted]

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: [redacted]
Basis: Submission does not estimate the number of workers potenitally exposed during this operation. RAD assesses a minimum default of [redacted] workers/site and that all workers perform all activities. RAD assumes that all workers may be exposed at the highest potential exposures for each physical form, as conservative.

Inhalation:

Air releases are negligible (VP < [redacted]) and generation of mists / aerosols is not expected during this operation.

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at [redacted] concentration

High End:

> Potential Dose Rate: [redacted]

> Lifetime Average Daily Dose: [redacted]

> Average Daily Dose: [redacted]

> Acute Potential Dose: [redacted]

Number of workers (all sites) with dermal exposure: [redacted]

Basis: Unloading Liquid Raw Material from Drums; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.